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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 03/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/848,771

Applicant(s)

ITO ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**FINAL ACTION**

1. This action is in response to papers filed 14 January 2003 in which claim 4 was amended and claims 5-8 were added. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of 16 August 2002 under 35 U.S.C. 102 and under 35 U.S.C. 103 are withdrawn in view of the amendments. The previous rejection under 35 U.S.C. 112, second paragraph is maintained. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 4-8 are under prosecution.

***Specification***

2. The amendment filed 14 January 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

New Claim 6 recites "repeatedly moving an injecting head of the inkjet device above the substrate". This recitation introduces new matter into the disclosure. The specification, on page 9, teaches producing a plurality of biochip by following production of a biochip, "the next plate is placed under the injection nozzle" thereby producing multiple biochips. Additionally, Figure 1 illustrates movement of the plate to thereby place a subsequent plate under the injection nozzle. However, the specification does not teach or illustrate the newly recited

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"repeatedly moving an injecting head of the inkjet device above the substrate". As such, the recitation introduces new matter into the disclosure.

New Claim 7 recites "repeatedly moving said biochip relative to an injecting head of the inkjet device and repeatedly injecting the first solution .....to different spots". This recitation introduces new matter into the disclosure. The specification, on page 9, teaches producing a plurality of biochip by following production of a biochip, "the next plate is placed under the injection nozzle" thereby producing multiple biochips. Additionally, Figure 1 illustrates movement of the plate to thereby place a subsequent plate under the injection nozzle. However, the specification does not teach or illustrate the newly recited "repeatedly moving said biochip relative to an injecting head of the inkjet device and repeatedly injecting the first solution .....to different spots". As such, the recitation introduces new matter into the disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

**35 U.S.C. 112: first paragraph**

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 6-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitations "repeatedly moving an injecting head of the inkjet device above the substrate" (Claim 6) and "repeatedly moving said biochip relative to an injecting head of the inkjet device and repeatedly injecting the first solution .....to different spots" (Claim 7) have been added. The specification fails to define or provide any disclosure to support such claim recitations. The specification, on page 9, teaches producing a plurality of biochip by following production of a biochip, "the next plate is placed under the injection nozzle" thereby producing multiple biochips. Additionally, Figure 1 illustrates movement of the plate to thereby place a subsequent plate under the injection nozzle. However, the specification does not teach or illustrate the newly added recitations. Therefore, the recitations constitute new matter.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE" (emphasis added).

**35 U.S.C. 112: second paragraph**

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 4-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-8 are indefinite in Claim 4 for the recitation "injecting the biochip-producing solution from the inkjet device" because it is unclear whether the solution is injected into the device or ejected from the device. It is suggested that the claim be amended to clarify as described in the specification e.g. replace "injecting" with "spotting" or "depositing".

Claims 4-8 are further indefinite in Claim 4 because the claim is drawn to a method for producing at least one biochip but the method does not recite steps which produce the biochip as claimed. It is suggested that Claim 4 be amended to recite steps of biochip production e.g. at the end of claim 4 insert "thereby producing a biochip."

Claims 5-7 are each indefinite for the recitations "injecting step", "injecting head" and "injecting the solution" because "injection" and "injecting" describe intake of a solution and now the expelling of solution required to produce the biochips. It is suggested that Claims 5-7 be amended to clarify.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch (U.S. Patent No. 6,083,763, filed 31 December 1997) in view of Italiano (U.S. Patent No. 4,380,772, issued 19 April 1983).

Regarding Claim 4, Balch teach a method for producing at least one biochip comprising putting a solution containing a biopolymer into an inject device and ejecting the solution from the ink jet device to a substrate to immobilize the biopolymer on a spot of a substrate of the biochip (Column 11, lines 33-65). Balch teaches the method utilizes known ink jet devices and technologies (Column 11, lines 40-54) but Balch does not specifically teach that two solutions of different gravity are placed into the ink jet device. However, ink jets comprising two solutions of differing gravity were well known in the art at the time the claimed invention was made as taught by Italiano. Italiano teaches that ink devices are supplied with two solutions wherein the second solution has a gravity smaller than the first solution and the two solutions are not mixed whereby all of the first solution is depleted (Column 3, lines 40-44) and wherein depletion of the first solution from the ink jet is identified by the presence and/or detection of the second solution (Column 2, lines 21-52). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the two solutions of Italiano to the ink jet deposition of Balch and to supply the ink jet with two solutions of differing gravity whereby depletion of the first (i.e. biopolymer) solution complete and is identified by the presence of the second solution as taught by Italiano (Column 2, lines 32-52). One of ordinary skill in the art would have been motivated to completely deplete the biopolymer solutions of

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Balch to thereby maximize biopolymer solutions by depositing all of the solution within the ink jet device and to thereby minimize the amount and cost of reagents required as desired by Balch (Column 11, lines 33-36).

Regarding Claim 5, Balch teaches the method wherein the ejecting steps include repeatedly replacing a biochip under the head of the inkjet device and ejecting the solution onto another biochip to thereby produce a plurality of biochips (Column 11, line 66-Column 12, line 12).

Regarding Claim 6, Balch teaches the method wherein the injecting step includes repeatedly moving the ink jet device above the substrate of another biochip thereby producing a plurality of biochips (Column 11, line 66-Column 12, line 12 and Fig. 3-4).

Regarding Claim 7, Balch teaches the method further comprising repeatedly moving the biochip relative to the ejecting head and repeatedly ejecting the first solution to different spots on the substrate (Column 11, line 66-Column 12, line 12 and Fig. 3).

Regarding Claim 8, Balch teaches the method wherein the ink jet device comprises biopolymers and the method utilizes known ink jet devices and technologies (Column 11, lines 40-54) but Balch does not specifically teach that two solutions of different gravity are placed sequentially into the ink jet device. However, ink jets comprising two solutions of differing gravity sequentially added to the ink jets were well known in the art at the time the claimed invention was made as taught by Italiano. Italiano teaches that ink devices are supplied with a first solution and then a second solution wherein the second solution has a gravity smaller than the first solution and wherein the solutions are added sequentially so as to not mix the two solutions (Column 2, lines 26-30). Italiano teaches that the two solution ink jet device provides for depletion of the first solution (Column 3, lines 40-44) and identification of the first solution depletion by the presence and/or detection of the second solution (Column 2, lines 21-52). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the two solutions of Italiano to the ink jet deposition of Balch and



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to supply the ink jet with two solutions of differing gravity whereby depletion of the first (i.e. biopolymer) solution complete and is identified by the presence of the second solution as taught by Italiano (Column 2, lines 32-52). One of ordinary skill in the art would have been motivated to completely deplete the biopolymer solutions of Balch to thereby maximize biopolymer solutions by depositing all of the solution within the ink jet device and to thereby minimize the amount and cost of reagents required as desired by Balch (Column 11, lines 33-36).

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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**Conclusion**

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
BJ Forman, Ph.D.  
Patent Examiner  
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March 26, 2003